REMARKS/ARGUMENTS

The above amendments have been provided based on the format described at 1265 Off. Gaz. Pat. Office 87 (December 17, 2002) and as authorized by Deputy Commissioner for Patents, Stephen Kunin on January 31, 2003.

Claim 29 has been amended to present the claimed subject matter using alternate phrasing with out altering the scope of the claim. The alternate phrasing emphasizes the fact that a *mixture*, of a photosensitizer dissolved in a carrier agent in liquid form, is combined at least one **solid support** not soluble in said carrier agent. Support for the amendment is found in the claim as originally presented, and no change of claim scope is intended or has occurred.

No new matter has been introduced, and entry of the amendment is respectfully requested.

Rejections under 35 U.S.C. § 1*02*

Claim 29 has been rejected under 35 U.S.C. § 102(b) as allegedly anticipated by Madden (USP 5,389,378). Applicants have carefully reviewed the statement of the rejection as well as the cited references and respectfully traverse.

The statement of the rejection asserts that the disclosure of lyophilized liposomes in the presence of lactose anticipate the claim. The statement also asserts that the enclosing of such liposomes in capsules anticipate the claim.

Applicants respectfully note that the instant rejection fails to present a *prima facie* case of anticipation of claim 29 because Madden entirely fails to disclose a "solid support not soluble in said carrier agent" as recited in the claim. Madden teaches the production of liposomes. The disclosed liposomes may be dehydrated (see for example col. 8, lines 64-68) in the presence of a sugar such as lactose (see for example col. 9, lines 1-30). But the disclosed sugars would be ***soluble*** in the liposomes before and during at least a portion of the dehydration process. This is evidenced

by the discussion of the sugars being "part of either the internal or external media" of the liposomes (see col. 9, lines 16-30). This passage treats the sugars as a "solute" rather than a ***solid***. Therefore, Madden fails to disclose the combination of a mixture in liquid form with a "solid support not soluble" in the mixture as required by the claim.

Similarly, Madden's discussion of capsule forms of liposomes is based on the encapsulation of lyophilized liposomes as recognized by the statement of the rejection. Therefore there is again no disclosure by Madden of a combination of a mixture in liquid form with a "solid support not soluble" in the mixture as required by the claim.

In light of the above deficiencies, Madden cannot anticipate the claim, and no *prima facie* case of anticipation is present. Withdrawal of this rejection is respectfully requested.

Claim 29 has also been rejected under 35 U.S.C. § 102(e) as allegedly anticipated by Desai et al. (USP 6,074,666). Applicants have carefully reviewed the statement of the instant rejection as well as the cited reference and respectfully traverse the rejection as failing to have presented a *prima facie* case of anticipation.

As with the case of Madden discussed above, Desai et al. also fail to teach the combination of a photosensitizer and carrier agent in liquid form with a "solid support not soluble in said carrier agent" as recited in the claim. The disclosure concerning lactose by Desai et al. is again of mixtures where the lactose would be soluble in the mixture.

Therefore, Desai et al. cannot anticipate the claim, and no *prima facie* case of anticipation is present. Withdrawal of this rejection is respectfully requested.

R*ejections under 35 U.S.C. § 103*

Claims 1-20 and 27-30 have been rejected under 35 U.S.C. § 103(a) as unpatentable over Lentini (USP 5,885,557) or Young et al. (USP 6,375,930) in light of Unger (USP 6,028,066). Applicants have carefully reviewed the statement of the rejection as well as the cited references and

understand the rejection to be based upon Lentini or Young et al. in the alternative and each in combination with Unger. Applicants respectfully traverse as follows.

The statement appears to assert that Unger's disclosure of the possible inclusion of a poloxamer is sufficient to meet all the limitations of the claims in light of either of the other two references. The rational appears to be based upon the assertion that the use of a poloxamer as a emulsifying and/or solubilizing agent need not be the same as the use of a poloxamer as a carrier agent as encompassed by the claims. Applicants **strongly** traverse this point because the actual amount of a poloxamer as a carrier agent as encompassed by the present claims is so different from the amount of the a poloxamer as used by Unger, that the instant claims are directed to a scope that does not encompass compositions as motivated by a combination of the cited references. The recitation of a block copolymer as carrier agent in the claims necessarily means that the agent is present in sufficient quantity to act as a carrier agent. Unger does not teach, suggest, or otherwise indicate such a quantity of their poloxamer.

Additionally, there is no teaching, suggestion or indication in any of the cited references of a combination of a mixture, of a photosensitizer and a block copolymer, and a ***solid support*** as required by the claims. The disclosure of a saccharide and polymers and polyvinyl pyrrolidone in Lentini and Young et al. are all in the context of these components being ***soluble*** in a photosensitizer composition which may then be dried. These components do not remain a **solid** support, as required by the claims, when they are used as disclosed by any of the cited references or a combination thereof. This was reflected in the previous response filed January 22, 2003 (mailed January 17, 2003) in Applicants assertion that there was no teaching of a solid support as required by the claims.

The fact that the disclosures of the cited references is different from the instant claims is even more evident in comparison to claims 2 and 7, which specifically recite that the "mixture is deposited on" the solid support. Because the saccharide and polymers and polyvinyl pyrrolidone in Lentini and Young et al. are all soluble in the context of those teachings, how can the mixture be "deposited on" a solute in solution?

Therefore, no *prima facie* case of obviousness is presented for the claims, and Applicants respectfully request that this rejection be withdrawn.

Claims 21-26 have been rejected under 35 U.S.C. § 103(a) as allegedly unpatentable over Lentini (USP 5,885,557) or Young et al. (USP 6,375,930) in combination with Unger (USP 6,028,066) or Desai et al. (USP 6,074,666) or Madden (5,389,378) and in light of Kataoka et al. (*J. Controlled Med.* 24:119-132, 1993). Applicants have carefully reviewed the statement of the rejection as well as the cited references and understand the rejection to be based upon Lentini or Young et al. in the alternative and each in combination with one of Unger, Desai et al. or Madden, and Kataoka et al. Applicants respectfully traverse as follows.

As an initial matter, Applicants note that the above discussion concerning the failure to disclose a **solid** support by any one of Lentini or Young et al. or Unger or Desai et al. or Madden, or any combination thereof, remains uncured in the instant rejection because Kataoka et al. do not disclose any solid support. This is again particularly evident for claims 2 and 7, which require that a mixture be deposited on a solid support.

Moreover, Applicants strongly traverse that the teachings of Kataoka et al. are sufficient to provide motivation to use unconjugated block polymers as recited in the claims. Applicants respectfully point out that the disclosure of Kataoka et al. must be limited to what it actually discloses: the use of certain conjugated block copolymers where "micelle formation is mainly driven through hydrophobicity and the cohesive force of the conjugated drug itself" (see page 123, right column). This clearly indicates that even Kataoka et al. do not envision the use of block copolymers as forming micelles capable of containing their drug (adriamycin). Therefore, the assertion that Kataoka et al. would motivate such a use of block copolymers is not supported by the reference itself. The first disclosure of such a use is apparently in the instant application, which cannot be used against Applicants for what it discloses.

Furthermore, and despite the use of the transition phrase "comprising" in the claims, the present invention is directed to the use of photosensitizers that are **not** conjugated to block copolymers as disclosed in the application as filed. In fact, the application includes the discussion that the compositions of the invention release a photosensitizer upon contact with blood plasma (see paragraph bridging pages 45 and 46 and Example 11). This is simply not possible if the photosensitizers are conjugated to a block copolymer in a manner analogous to Kataoka et al. How would the covalent bond be severed? Where is the expectation of success of using a photosensitizer that is conjugated to a block copolymer?

With respect to the assertion that "Kataoka clearly states that the block copolymer as a vehicle for drug delivery which implies any drug and that the polymer is a carrier agent", Applicants strongly disagree with the allegation of what Kataoka et al. "implies". There is no evidence of record to support that one of ordinary skill in the art would have viewed Kataoka et al. as making such an "implication". To the contrary, there is evidence, as noted above, that Kataoka et al. themselves viewed their observations as being the result of the particular drug conjugated system that they used.

Last, and contrary to the assertion in the statement of the rejection, the discussion in col. 1, page 123 of Kataoka et al. provides no clear guidance that block copolymers can be used to generally entrap a drug compound into the core of a micelle. The discussion of "physical entrapment" and "covalent binding" are in the last three sentences of col. 1, which relate to the following section describing the use of drug conjugated block copolymers.

In light of the above discussion, Applicants respectfully submit that the limitations of the claims are not fully disclosed in the cited references, alone or in combination, and that no reasonable expectation of success exists for a combination of the cited references to result in the instantly claimed invention. Therefore, no *prima facie* case of obviousness exists, and the instant rejection may be properly withdrawn.

Conclusion

In light of the above amendments and remarks, Applicant respectfully submits that claims 1-30 may be allowed, and this application moved toward issuance. The Examiner is encouraged to contact the undersigned if he determines that further discussions would prove useful in response to the Office Action dated March 27, 2003 (Paper No. 11)

In the unlikely event that the transmittal letter is separated from this document and the Patent Office determines that an extension and/or other relief is required, Applicant petitions for any required relief including extensions of time and authorizes the Assistant Commissioner to charge the cost of such petitions and/or other fees due in connection with the filing of this document to **Deposit Account No. 03-1952** referencing docket no. 273012011700.

Dated:

Respectfully submitted,

By_____

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